IN THE UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF GEORGIA SAVANNAH DIVISION

JOHN D. CARSON, SR.,)
Plaintiff,))
v.) Case No. 4:17-cv-00237-RSB-CLR
MONSANTO COMPANY,))
Defendant.)

REPLY IN SUPPORT OF DEFENDANT MONSANTO COMPANY'S MOTION FOR $\underline{\textbf{JUDGMENT ON THE PLEADINGS}}$

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INTRODUCTION

Plaintiff admits that he seeks to "contradict[]," Opp. 15, the registration decisions and scientific judgments of the Environmental Protection Agency ("EPA") regarding the labeling for Roundup®. But as a matter of federal law, EPA decides what warnings are appropriate—and that decision is binding. Nothing in Plaintiff's opposition addresses, much less refutes, what the U.S. Government has clearly explained: under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), "the label is the law." Ex. B, ECF No. 37-3, Br. for U.S. as Amicus Curiae Supporting Appellant at 1, Monsanto Co. v. Hardeman, No. 19-16636 (9th Cir. Dec. 20, 2019). Neither does Plaintiff acknowledge EPA's express confirmation that it would not approve a warning that glyphosate causes cancer, and that including such a warning would make a product misbranded in violation of the requirements of FIFRA. Ex. A, Doc. 37-2, EPA, Off. of Pesticide Programs, Letter to Glyphosate Registrants Regarding Labeling Requirements at 1 (Aug. 7, 2019). Just last month, after spending years "thoroughly evaluat[ing] potential human health risk associated with exposure to glyphosate," EPA conclusively reaffirmed that "there are no risks to human health from the current registered uses of glyphosate and that glyphosate is not likely to be carcinogenic to humans." Ex. 1 (attached), EPA, Glyphosate: Interim Registration Review Decision Case No. 0178, at 10 (Jan. 2020). Plaintiff cannot avoid preemption by simply disregarding the authoritative actions of an expert federal agency performing the role assigned to it by Congress.

Plaintiff's other strategy to avoid preemption is to obscure the central theory of liability pled in his complaint. Plaintiff repeatedly alleges that he would not have been injured "[h]ad Defendant provided adequate warnings" on the label. Compl. ¶ 100. Yet now Plaintiff acts as though his case has little to do with warnings on Roundup®'s EPA-approved label. This gambit fails many times over. A review of the complaint's actual allegations confirms that the adequacy of the warnings on the Roundup® label is foundational to every claim. To the extent Plaintiff

purports to bring some non-warning-based claim, he has not adequately pled one—a point made in Monsanto's motion and for which Plaintiff has no response. And even if there were well-pled, non-warning-based claims in this case, they would still be preempted.

All of Plaintiff's claims, however styled, are preempted and should be dismissed.¹

ARGUMENT

I. FIFRA Expressly Preempts Plaintiff's Claims Because They Are Based on a Purported State-Law Labeling Requirement That Is in Addition to, and Different From, What FIFRA Requires.

Plaintiff does not ultimately disagree with Monsanto on the legal standard governing express preemption: FIFRA preempts a claim if it is based on a "requirement for labeling or packaging," and if that requirement is "in addition to or different from" a requirement under FIFRA. Opp. 6 (quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 444 (2005)); *accord* Mot. 14–15.² Plaintiff does not dispute that one of his claims—Failure to Warn—fits squarely within the first part of the standard, arguing instead that the state-law labeling requirement is "equivalent" to FIFRA. Opp. 13. He further argues that his other three claims are challenges to Roundup®'s composition and not its labeling. Opp. 12–14. On both fronts, Plaintiff is incorrect.

Plaintiff asserts without elaboration that Monsanto's motion is untimely based on the time between the filing of the complaint and Monsanto's Rule 12(c) motion. Opp. 5. But the Rule is clear that timeliness of a motion for judgment on the pleadings has nothing to do with the time elapsed *after* the complaint, but rather the time remaining *before* trial: the only requirement is for the motion to be filed "early enough not to delay trial." Fed. R. Civ. P. 12(c). Plaintiff has not attempted to explain how this motion would delay trial. Nor could he, given that the case remains at an early stage and no trial date has even been set.

² Plaintiff quotes portions of two district court opinions—one issued before *Bates* and one issued shortly after—and relies on a handful of pre-*Bates* opinions to set out the applicable legal standard. Opp. 9–11 (first quoting *Gougler v. Sirius Prods., Inc.,* 370 F. Supp. 2d 1185, 1197 (S.D. Ala. 2005), then quoting *Hughes v. S. States Co-Op, Inc.,* 180 F. Supp. 2d 1295, 1298–99 (M.D. Ala. 2001)). But Plaintiff agrees that *Bates* established the test for determining whether a state law claim is expressly preempted by FIFRA, and nothing in the other decisions cited by Plaintiff changes the analysis.

A. Plaintiff's "Failure to Warn" Claim (Count 2) Is Preempted.

Most of Plaintiff's opposition attempts to minimize the extent to which his case is about the lack of a cancer warning on Roundup®'s labeling. Plaintiff does not, however, make this argument with respect to his failure to warn claim. *See* Opp. 13. Indeed, Plaintiff concedes that FIFRA's express preemption provision applies to claims "predicated on failure to warn." *Id.* at 14 (citing *Gougler*, 370 F. Supp. 2d at 1194). Nor can there be any question that a claim challenging the adequacy of "warnings disseminated with [Monsanto's] Roundup® products," Compl. ¶ 94, is a challenge to those products' labeling. *See* 7 U.S.C. § 136(p)(2)(A) (defining "labeling" to mean "all labels and all other written, printed, or graphic matter accompanying the pesticide or device at any time").

Unable to dispute that his failure to warn claim is based on a state-law labeling requirement, Plaintiff complains that Monsanto has not "cite[d] to the relevant Georgia state law" or "compare[d]/contrast[ed] Georgia law with FIFRA." Opp. 13. But it is obvious what *Plaintiff* believes Georgia law requires—a cancer warning on Roundup®. The "compare and contrast" between state law and federal law is simple, and the differences stark. Georgia law, according to Plaintiff, requires Monsanto to warn that Roundup® is carcinogenic. Federal law, by contrast, does not require Monsanto to warn that Roundup® is carcinogenic—and indeed prohibits Monsanto from issuing such a warning. *See* Mot. 17–20. Thus, the purported Georgia law labeling requirement that is the basis of Plaintiff's claim is hardly "equivalent to that of FIFRA." Opp. 13. It is plainly incorrect to suggest that "the requirements imposed on [Monsanto] under state and federal law do not differ." *Bates*, 544 U.S. at 448.

At bottom, Plaintiff's argument that his state-law labeling requirement is "equivalent" to the requirements of FIFRA ignores EPA's central role in the statutory scheme. When the Supreme Court held that a state-law claim could survive preemption only if it were "equivalent to, and fully

consistent with, FIFRA's misbranding provisions," it recognized that EPA's application of those provisions has controlling preemptive force. *Id.* at 447. Thus, *Bates* explained, state law may not require a product to be labeled "DANGER" if EPA has determined the product should have a more-subdued "CAUTION" warning. *Id.* at 453. Here, Plaintiff's divergence from the EPA's application of FIFRA's misbranding prohibition is even more stark—asserting that the product's labeling is deficient because it fails to include a cancer warning that EPA has consistently and explicitly rejected.

Plaintiff's suggestion that EPA's determinations are irrelevant, *see* Opp. 15, is also foreclosed by *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), which concerned "a similarly worded pre-emption provision" in the Medical Devices Act of 1976, 21 U.S.C. § 360k, and a similar statutory scheme under which FDA grants premarket approval to medical devices through safety and labeling review. *See Bates*, 544 U.S. at 447; *Riegel*, 552 U.S. at 322–23. In *Riegel*, the Supreme Court held that FDA's premarket approval of a medical device triggered labeling "requirements" under the Federal Food, Drug, and Cosmetic Act specific to that device, thereby preempting any additional or different state-law requirements. 552 U.S. at 322–23. The same is true here: EPA's approval of Roundup® labeling, following an exacting review of glyphosate's potential health risks (including carcinogenicity), triggered specific federal labeling requirements that preempt *any* additional or different state-law requirements.

Plaintiff also fails in his attempt to manufacture a disputed "question of material fact," claiming "a real debate between health, cancer and governmental organizations and the EPA as to the safeness of glyphosate." Opp. 14–15. Even if the existence of such a debate is a fact,³ it is not

³ Any such "debate" is extraordinarily one-sided. EPA has repeatedly undertaken in-depth scientific reviews of glyphosate's safety based on extensive reviews of scores of studies. Each time—since at least 1991—EPA has concluded that glyphosate is non-carcinogenic. Virtually

a material one. EPA's decisions to approve Roundup® registrations without a cancer warning, and its repeated and consistent scientific determinations that such a warning would be inaccurate, are not facts in dispute—they are authoritative agency actions with legal consequences under FIFRA.

B. Plaintiff's Other Three Claims Are Also Based on a Failure to Warn and Are Preempted for the Same Reasons.

At a minimum, Count 2 of Plaintiff's complaint is expressly preempted and should be dismissed. Careful assessment of Counts 1, 3, and 4 demonstrates that they are subject to the same analysis.

Count 1: Design Defect. Plaintiff insists that his design defect claim "rests upon the product's defective design and formulation." Opp. 12. Yet under Georgia law, warnings are "part of the total design package of the product," Boyce v. Gregory Poole Equip. Co., 605 S.E.2d 384, 390 (Ga. Ct. App. 2004), so a claim of "defective design" can be based on a requirement to issue a warning. Mot. 16 n.7. And the specific allegations of the complaint confirm that this is Plaintiff's theory. Under the heading of his design defect claim, Plaintiff alleges that Roundup® products were unreasonably dangerous "as . . . labeled." Compl. ¶¶ 68–69, 71. He alleges that Roundup® is "inherently dangerous and unsafe when used in the manner instructed and provided by Defendant." Id. ¶ 70 (emphasis added). And his fundamental objection—again, under the rubric of his design defect claim—is not to the Roundup® products' formulation alone, but that he used them "without knowledge of their dangerous characteristics." Id. ¶ 72 (emphasis added).

Plaintiff's reliance on *Bates*, *see* Opp. 12–13, is misplaced. In holding that the design defect claims at issue there were not preempted, the Court did not rely on the title of the claim but

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every national and international agency charged with reviewing and approving pesticides agrees with EPA's determination. *See* Mot. 10–12.

on its substance. The Court rejected an argument that the design defect claim related to labeling because, if successful, it would "induce a manufacturer to alter its label to reflect a change in the list of ingredients." 544 U.S. at 445. The question for express preemption purposes was not whether a successful claim might incidentally require a change in the product's label, but instead whether the claim itself explicitly or implicitly challenged the existing label. And in *Bates*, the design defect claim did not challenge the labeling because the purported requirement—to change ingredients—did not concern the sufficiency of labeling. Here, in contrast, where the design defect claim ultimately challenges the adequacy of warnings as "part of the total design package of the product," *Boyce*, 605 S.E.2d at 390, such a claim does seek to enforce a state-law labeling requirement.

Count 3: Negligence. Plaintiff asserts that his "negligence claim is NOT predicated upon Defendant's labeling." Opp. 14. Again, this assertion is inconsistent with the complaint. According to that complaint, Monsanto's "duty of care . . . included providing accurate, true, and correct information concerning the risks of using Roundup® and appropriate, complete, and accurate warnings concerning the potential adverse effects of exposure to Roundup®, and, in particular, its active ingredient glyphosate." Compl. ¶ 105. The complaint then alleges that Monsanto "breached its duty of reasonable care" because it knew that Roundup® created a risk of harm "and failed to prevent or adequately warn of these risks and injuries." Id. ¶ 109 (emphasis added); see also id. ¶ 116 (alleging that Plaintiff's injury was the "proximate result" of Monsanto's actions placing Roundup® "into the stream of commerce without adequate warnings of the hazardous and carcinogenic nature of glyphosate"). Even the one paragraph of the complaint that Plaintiff quotes in his opposition refers to Roundup®'s "packaging." Opp. 14 (quoting Compl. ¶ 104).

Again, contrary to Plaintiff's suggestion, *Bates* did not "f[i]nd negligence" claims "not to be preempted." Opp. 14. The Court held that a "negligent *testing*" claim was not preempted, but that the "negligent-*failure-to-warn* claims are premised on common-law rules that qualify as 'requirements for labeling or packaging'" that may not be "in addition to or different from" requirements under FIFRA. 544 U.S. at 444, 446–47 (emphasis added). As Plaintiff's complaint confirms, his claim is the latter kind.

Count 4: Breach of Implied Warranties. The same is true of Plaintiff's implied warranty claim. To argue that this claim is not based on the adequacy of the warnings on the EPA-approved label, Plaintiff cites paragraph 119 of his complaint, which simply alleges that Monsanto made an implied warranty to its consumers. The next paragraph alleges how Plaintiff believes Monsanto violated that warranty: "Defendant, however, failed to disclose that Roundup® has dangerous propensities when used as intended and that the use of and/or exposure to Roundup® and glyphosate-containing product carries an increased risk of developing severe injuries, including Plaintiffs injuries." Compl. ¶ 120 (emphasis added).

Yet even if Plaintiff were correct in characterizing Counts 1, 3, and 4 as focused on Roundup®'s formulation rather than its labeling, that does not mean that he has *adequately pled* such a claim. To the contrary, Monsanto's motion explained the requirements for properly stating a design defect claim, and why Plaintiff's conclusory allegations fail to do so. Mot. 16 n.7. The same failure applies equally to his other claims to the extent they are based on a challenge to Roundup®'s design. *See Davis v. John Crane, Inc.*, 836 S.E. 2d 577, 583 (Ga. Ct. App. 2019) (relying on the elements of a design defect claim to assess a claim for negligent product design because "[i]n Georgia, only semantics distinguishes the cause of action for negligence and a cause

of action pursuant to OCGA § 51-1-11 (claiming strict liability for defective design)" (quotation marks omitted)). Plaintiff has offered no response.

In short, the linchpin of each of Plaintiff's claims is that Roundup® lacked adequate warnings on its labeling. For the same reasons explained above and in Monsanto's motion, *supra* pp. 2–7; Mot. 17–20, the purported state-law requirement to issue such warnings is in addition to, and different from, the federal law requirement *not* to issue such warnings. Accordingly, FIFRA expressly preempts all of Plaintiff's claims.

II. Impossibility Preemption Bars All of Plaintiff's Claims.

Plaintiff's claims also fail under principles of impossibility preemption, for two independent reasons. First, there is clear evidence that EPA would reject the cancer warning that Plaintiff contends state law requires, and so would not allow Monsanto to issue such a warning. See Wyeth v. Levine, 555 U.S. 555 (2009); Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668 (2019). Second, Monsanto cannot unilaterally change Roundup®'s label—or its formulation—without prior agency approval. See PLIVA, Inc. v. Mensing, 564 U.S. 604 (2011); Mut. Pharm. Co., Inc. v. Bartlett, 570 U.S. 472 (2013).

A. Plaintiff's Claims Are Preempted Because There Is "Clear Evidence" That EPA Would Not Approve a Cancer Warning.

Under the standard established in *Wyeth* and *Albrecht*, there is "clear evidence" that a federal agency would reject a proposed warning if the agency was "fully informed" of the warning's "justifications," and the agency nonetheless determined that it "would not approve" such a warning. *Albrecht*, 139 S. Ct. at 1678. Here, there is no dispute of material fact as to either: EPA has conducted extraordinarily comprehensive reviews of the relevant data, *see* Mot. 22, and time and again has concluded that glyphosate does not pose a cancer risk and that a warning of such a risk would be inappropriate, *see id.* at 22–23.

Plaintiff's response is simply to criticize EPA. According to Plaintiff, "Defendant's argument rests upon the factual notion that the EPA's reports are correct and incapable of contradiction." Opp. 15. But the actual premise of Monsanto's argument—and of impossibility preemption—is that *Monsanto* is not permitted to contradict the agency's scientific judgment and binding registration and labeling decisions. Under *Wyeth* and *Albrecht*, the Court's charge is to ascertain whether there is clear evidence that the agency would have rejected the warning. Because such clear evidence exists here, Plaintiff may not ask the Court to second-guess that scientific judgment.⁴

Plaintiff apparently disagrees with how EPA has performed its congressionally assigned role. But he does not (and cannot) dispute the three basic points that control the impossibility analysis: (1) EPA has repeatedly and consistently confirmed its determination that glyphosate is not likely to be carcinogenic to humans; (2) as a result of its scientific findings, EPA has rejected the cancer warning that Plaintiff says state law requires; and (3) federal law prohibits Monsanto from adding a cancer warning without EPA's approval. Even if Plaintiff believes "EPA's reports are riddled with holes," Opp. 15, it remains "impossible for [Monsanto] to comply with both state and federal requirements." *Albrecht*, 139 S. Ct. at 1672 (quoting *Bartlett*, 570 U.S. at 480).

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⁴ Plaintiff also accuses the EPA's process of being "corrupted" by Monsanto, alleging that some "testing was funded by Monsanto and therefore highly criticized." Opp. 2–3, 15. But EPA itself has confirmed the "independent" nature of its evaluation, "subject to an internal peer review process and scientific review committees within the Office of Pesticide Programs to ensure accuracy and consistency of interpretation." Ex. E, ECF No. 37-6, EPA, Glyphosate Proposed Interim Registration Review Decision at 8. EPA also relies on a host of information and data not provided by registrants. *See id.* at 8–9. Notably, Plaintiff's allegations of improper influence by Monsanto are similar to comments that have been submitted to EPA itself as part of its review process, and EPA's position has not changed. *See* Ex. 2 (attached), Nat'l Res. Defense Council, Comments on Draft Human Health and Ecological Risk Assessment for Glyphosate, EPA-HQ-OPP-2009-0361-0066, at 5 (Apr. 30, 2018) (asserting "communication and collaboration between Monsanto" and EPA); Ex. 3 (attached), EPA, Response from the Pesticide Re-evaluation Div. (PRD) to Comments on the Glyphosate Proposed Interim Decision at 2 (Jan. 16, 2020) (stating that the comments submitted to EPA "did not result in changes to the agency's risk assessment").

B. Plaintiff's Claims Are Also Preempted Because Monsanto Cannot Unilaterally Alter Roundup®'s EPA-Approved Labeling—or Its Formulation.

Plaintiff does not even respond to Monsanto's argument that his claims are preempted because Monsanto cannot "independently do under federal law what state law requires of it." *Mensing*, 564 U.S. at 620; *see* Mot. 23–24. As Monsanto explained, EPA regulations prohibit the label changes that Plaintiff says were required without the agency's prior approval. *Id.* Plaintiff does not disagree.

In his opposition, Plaintiff has minimized his complaint's focus on the adequacy of warnings on the Roundup® products' EPA-approved label, and instead has sought to characterize his case as relying on the products' formulation and design. As explained above, this argument is inconsistent with the complaint. *Supra* pp. 2–7. It also fails because any attempt to allege non-warning-based design defects is not well-pled. *Supra* pp. 7–8. But to the extent Plaintiff has pled a claim that the Roundup® products should have been formulated differently, such claims are still preempted.

"The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *Mensing*, 564 U.S. at 620; *see also Gustavsen v. Alcon Labs., Inc.*, 903 F.3d 1, 9 (1st Cir. 2018) ("If a private party . . . cannot comply with state law without first obtaining the approval of a federal regulatory agency, then the application of that law to that private party is preempted."). That is unquestionably the case here. Under FIFRA, a pesticide manufacturer cannot independently change the composition of its product—prior EPA approval is required. *See* 40 C.F.R. § 152.44(a) ("Except as provided by § 152.46, any modification in the composition, labeling, or packaging of a registered product must be submitted with an application for amended registration"); *id.* § 152.46 (exception only for "certain minor modifications"); *see also* EPA Pesticide Registration Notice 98-10, at 14 (Oct. 22, 1998), *available*

at https://www.epa.gov/sites/production/files/2014-04/documents/pr98-10.pdf ("[A] formulation change may only be accomplished through submission of an application for amended registration").

In the drug manufacturing context, similar regulations prohibit major changes to a drug's design without FDA approval. *See* 21 C.F.R. § 314.70(b). On that basis, courts have held that design defect claims against drug manufacturers are preempted. Specifically, if a plaintiff claims a design defect arguing that state law required a drug manufacturer to make what qualifies as a major change to its product, "federal law preempts [that] cause of action because defendants cannot lawfully make such a change without prior FDA approval." *Gustavsen*, 903 F.3d at 10.

In *Bartlett*, the Supreme Court held that design-defect claims brought against generic drug manufacturers are preempted when manufacturers cannot unilaterally change their drug's design. 570 U.S. at 475–76. Numerous courts have applied the same reasoning to design-defect claims against brand-name manufacturers: the allegedly necessary product change requires prior FDA approval, so a state-law design defect claim based on failure to make that change is preempted. *See, e.g., Gustavsen*, 903 F.3d at 10.⁵

The Sixth Circuit's decision in *Yates v. Ortho-McNeil-Janssen Pharmaceuticals* is particularly instructive. 808 F.3d 281 (6th Cir. 2015). In *Yates*, the plaintiff argued that the

⁵ See also Drescher v. Bracco Diagnostics Inc., No. CV-19-00096-TUC-RM (LCK), 2020 WL 699878, at *7–9 (D. Ariz. Jan. 31, 2020); Greager v. McNeil-PPC, Inc., 414 F. Supp. 3d 1137, 1140–41 (N.D. Ill. 2019); Ridings v. Maurice, No. 15-00020-CV-W-JTM, 2019 WL 4888910, at *5–7 (W.D. Mo. Aug. 12, 2019); Robinson v. Eli Lilly & Co., 5:17-CV-338-KKC, 2018 WL 4039703, at *6 (E.D. Ky. Aug. 23, 2018); Kwasniewski v. Sanofi-Aventis U.S. LLC, No. 2:12-cv-00515-GMN-NJK, 2018 WL 1567851, at *5 n.4 (D. Nev. Mar. 30, 2018); Batoh v. McNeil-PPC, Inc., 167 F. Supp. 3d 296, 321–22 & n.19 (D. Conn. 2016); Brazil v. Janssen Research & Dev. LLC, 196 F. Supp. 3d 1351, 1363 (N.D. Ga. 2016); Barcal v. EMD Serono, Inc., No. 5:14-cv-01709-MHH, 2016 WL 1086028, at *4 (N.D. Ala. Mar. 21, 2016); Thompson v. Allergan USA, Inc., 993 F. Supp. 2d 1007, 1013–14 (E.D. Mo. 2014); Trejo v. Johnson & Johnson, 13 Cal. App. 5th 110, 154–55 (2017) (same).

manufacturer of a brand-name estrogen patch "should have altered the formulation of [the product] after the FDA had approved the patch," or that it should have "adopt[ed] a safer design" before approval. *Id.* at 298–99. Plaintiff noted that products on the market in other countries showed that an alternative design was available. *Id.* at 299. Moreover, there was "no evidence that the FDA would have exercised its authority to prohibit defendants from creating and submitting such a design for approval." *Id.* The court nonetheless found the claims preempted. The "post-approval design defect claim" was "clearly preempted by federal law," because "prior FDA approval [was] necessary" to make the demanded formulation change. *Id.* at 298. And the "pre-approval claim" "essentially argues that defendants should never have sold the FDA-approved formulation . . . in the first place." *Id.* at 300. This "never-start selling rationale" failed "for the same reasons the Supreme Court in *Bartlett* rejected the stop-selling rationale." *Id.*; *see Bartlett*, 570 U.S. at 488.

Just as redesign was not legally possible for the drug manufacturers in *Yates* without FDA approval, so too was it not legally possible for Monsanto to redesign Roundup® without EPA approval. Any claim that Monsanto violated state law by failing to redesign Roundup®—by changing its EPA-approved formulation—is preempted for the same reasons.

CONCLUSION

For the foregoing reasons, this Court should grant Defendant's motion for judgment on the pleadings under Fed. R. Civ. P. 12(c) and dismiss the complaint with prejudice.

Dated: February 28, 2020 Respectfully submitted,

/s/ Martin C. Calhoun

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 28th day of February, 2020, a copy of the foregoing was filed with the Clerk of the Court through the CM/ECF system, which will generate an electronic notification and effect service on all counsel of record.

/s/ Martin C. Calhoun

Counsel for Defendant Monsanto Company